Manufacturer's Self-Declaration

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Vitalograph (Ireland) Ltd
Manufacturer address and contact details	Gort Road Business Park, Ennis, Co. Clare, Ireland V95 HFT4
Single Registration Number (SRN)	IE-MF-000004858

Authorised Representative name (if applicable)	N/a
Authorised Representative address and contact details	N/a
Single Registration Number (SRN)	N/a

Notified body name	BSI	□ See attached schedule
Notified body number	2797	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made	CE 00772 & CE 85553	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	26 May 2024 for both	□ See attached schedule
End date of extended validity/transition period	31 Dec 2028 for both	□ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a Notified Body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a Notified Body.

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Registered Office:
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Company Registration Number:
48600

Directors
B R Garbe (UK) | M J Garbe (UK)
F J Keane | K J Moore | H E Venn (UK)

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificates** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

Directive Certificate(s) as listed above:
Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards. These certificates expire after 20 March 2023.

Formal application(s) to the Notified Body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made for the devices listed in the attached schedule or their substitutes and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

Quality Management System (QMS)
A QMS in accordance with Article 10(9) MDR is in place.

Devices as listed in the attached schedule

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name
Vitalograph (Ireland) Ltd

Location & Date
Gort Road Business Park, Ennis, Co. Clare, Ireland V95 HFT4 & 25/Mar/2024

Signature, Print Name, Title
_____ James O'Keeffe, CTO & PRRC

Contact Details (email and Telephone No)
james.okeeffe@vitalograph.ie 00353 65 6864100

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a Notified Body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a Notified Body

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (device model)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s) (if applicable)
SafeTway Mouthpiece (2024)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Electronic Spirometer (2120)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Electronic Spirometer (2150)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Bacterial Viral Filter (2820)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Electronic Spirometer (4000)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
ECG Device (4130)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Manual Peak Flow Meter (4300)	CE 85553	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Electronic Spirometer (6000)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Electronic Spirometer (6300)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Electronic Spirometer (6600)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Electronic Spirometer (6800)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Electronic Spirometer (7000)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Cough Monitor (7100)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a
Pulmonary Function Test devices (9100)	CE 00772	26 May 2024	BSI 2797 (formerly 0086)	BSI 2797	31 Dec 2028	N/a

[3] for devices with MDD certificates the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

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